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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,935	COX ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,25 and 33-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12, 25, 33-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *4/19/04*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment

1. Applicant's amendment filed on 7/26/04 is acknowledged. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Status of claims

2. Claims 11 and 26-32 have been canceled.

New Claims 33-45 have been added.

Claims 1-10 and 12-25 and 33-45 are pending in the application.

Drawings

3. The corrected drawings are accepted by the Examiner.

Claim Rejections- 35 USC 112, first paragraph maintained

4. The rejection of claims 1-2, 7-10, and 12 - 25 under 35 U.S.C. 112, first paragraph, is maintained as set forth in the previous office action.

The claims are drawn to an isolated nucleic acid segment or a composition or a vaccine comprising at least a first isolated coding region that encodes a first peptide of between 18 and about 24 amino acids in length that comprises an amino acid sequence that is at least about 88% or 94% identical to the amino acid sequence of SEQ.ID.NO: 2, said nucleic acid encoding the amino acid sequence, SEQ.ID.NO: 2 or nucleic acid sequence, SEQ.ID.NO: 1 said segment is defined as recombinant vector in a recombinant host cell. The recombinant host cell further comprises at least a second isolated coding region that encodes a second, distinct Coccidioides spp. Protein, polypeptide or peptide. The examiner is considering peptides with 88% or 94% as fragments/variants of said sequences.

The nature of the disclosed invention is drawn to an isolated recombinant nucleic acid molecule or a composition or a vaccine that encodes the amino acid sequence SEQ ID NO: 2 or nucleic acid sequence SEQ.ID.NO: 1 in a recombinant vector transformed in a host cell expressing peptide or protein. The nucleic acid segment further comprises a second, distinct Coccidioides peptide. The specification teaches that immunization with full-length Ag2/PRA recombinant protein (pVR1012-Ag2 1-194) or with truncated Ag2/PRA polypeptide (pVR1012-Ag2 19 -194) and the signal sequence Ag2/PRA 1-18 (pVR1012 Ag21-18) induce protection against challenge infection C.immitis (figures 7 and 8) in animals. However, the specification fails to teach any description of any such signal sequence (Ag2/PRA 1-18) fragments /variants of SEQ.ID.NO: 2 that are able to function as Ag2/PRA 1-18 (pVR1012-Ag2 1-18) against

challenge infection or even be able to express a peptide that is suitable for immunizations or bind to antibodies raised against peptide 1-18 and provides no working examples demonstrating (i.e., guidance) enablement for any fragments/variants and uses of the claimed fragments/variants as a vaccine composition.

The state of the prior art indicates that protein chemistry is probably one of the most unpredictable areas of biotechnology and is highly complex. As taught by the prior art (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6), the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted a priori and must be determined empirically on a case by case basis. The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen ((Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of a single amino acid residue may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which products proteins that differ in native conformation, immunological recognition, binding and thus exemplifying the importance of structural components to both biological and immunogical function. Thus, use of fragments/variants must be considered highly unpredictable, requiring a specific demonstration of efficacy on a case-by-case basis. Absent such demonstration, the invention would require undue experimentation to practice as claimed. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed fragments/variants in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made in the protein renders activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

5. Applicants' arguments filed on 7/26/04 have been fully considered but they are not deemed to be persuasive for the following reasons:

Applicant states that the office action is concerned with the % identity language included in the claims and the claims cover peptides with only minimal amino acid changes from SEQ ID NO: 2. Given the very moderate scope of the claims, the detailed teaching in the specification and the high level of technical skill in the art, the action has not met the burden required to

support a prima facie rejection and cites In re Marzocchi & Horton, 169 USPQ 367 (CCPA 1971) in support.

The examiner would like to point to the Applicant that the claims are not restricted to the specific peptides of SEQ.ID.NO: 2 (isolated polypeptide consisting of --) As claimed, the claims are drawn to a broader genus of SEQ.ID.NO: 2 because an isolated nucleic acid comprising (open language) at least a first isolated coding region that encodes a peptide of between 18-24 amino acids in length that comprises ----SEQ.ID.NO: 2 plus unlimited number of unknown amino acids read on peptide which is larger than SEQ.ID.NO: 2. Thus, the specification does not support the broad scope of the claims which encompass peptides of SEQ.ID.NO: 2 having 18-24 amino acids of SEQ.ID.NO: 2 plus unlimited number of amino acids because the specification does not establish the structure or function as claimed.

Applicant states the specification enables the scope of the claims in the manner required by Wands. Applicant further states that the Action cites Rudinger, 1976; Burgess et al., 1990; Lazar et al., 1988, and Jobling & Holmes, 1991 in an attempt to support the rejection (Action at pages 4-5), none of these references are effective to cast doubt on the enabling teaching in the specification. In addition, it is noted that the references relied upon are from 1976, 1990, 1988 and 1991, the most recent of which is still ten years before the priority date of the present application, and that the level of technical skill in the art has advanced during this time.

The examiner disagrees with the applicant because the specification does not teach how to use the peptides as claimed, therefore, guidance of making and using such broadly claimed fragments in the form of working examples would support the enablement requirement as stated in the previous office action. The examiner is aware of hybridoma technology using peptide epitopes. However, Applicant is not claiming an isolated peptide consisting of 18-24 contiguous amino acids of SEQ.ID.NO: 2 as hybridoma technology use short peptides for screening

antibodies. The examiner is aware and understands the level of technical skill in the art as the state of the art in biotechnology area has advanced. However, the protein chemistry has not changed over the years. For example: It has been known since 1958, a single amino acid replacement (valine instead of glutamic acid at position 6 in the haemoglobulin chain) causes sickle cell anemia (SCA) 1958) and the same is true till today. This indicates that protein chemistry has not changed during all these years even though the level of technical skill in the art of SCA screening and identifying SCA associated diseases has advanced over the years. Therefore, the examiner believes the art used was appropriate and rightly supports the examiner's position for enablement issue. For the reasons of record this rejection is maintained.

Claim Rejections - 35 USC 112, second paragraph maintained

6. The rejection of claims 1-10 and 12-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained as set forth in the previous office action.

Applicant states that the phrases "between 18 and about 24 amino acids", "at least about 88%'. and "at least about 94%" and " distinct" are used according to its ordinary and customary meaning and the specification does not use this term in a manner other than its ordinary meaning. Thus, there is no special definition attached to these phrases. Further applicant states that the use of the term "about" and "at least about" per se is completely acceptable. The fact that some claim language is not precise does not automatically render a claim indefinite and again cites case law.

It is the examiner's position that while the use of "about" is acceptable, when used with "between 18 and about 24 amino acids" and the transitional limitation "comprises" leaves the claim open for the inclusion of unspecified ingredients even in major amounts and thus renders

the claim confusing and indefinite. It is not clear whether 1-18 or 1-19 or 1-24 or total 7 amino acids between 18-24 are being claimed.

The limitation "at least " in the claims does not limit to SEQ.ID.NO: 2 or 1 and reads on any nucleic acid segment or any first coding region.

The term "distinct" makes the claim vague because the first isolated coding region does not refer to specific Coccidioides spp. Therefore, these rejections are maintained.

Claim Rejections - 35 USC 102 maintained

7. The rejection of claims 1-8, 13, 14, 16- 19 under 35 U.S.C. 102(b) as being anticipated by Dugger et al (Biochemical and Biophysical Research Communications 218; 485-489), Accession number: U39835 is maintained as set forth in the previous Office action.

The examiner regrets the inconvenience caused by sending the sequence alignment late.

The claims are drawn to an isolated nucleic acid segment or a composition or a vaccine comprising at least a first isolated coding region that encodes a first peptide of between 18 and about 24 amino acids in length that comprises an amino acid sequence that is at least about 88% or 94% identical to the amino acid sequence of SEQ.ID.NO: 2, said nucleic acid comprises either encoding the amino acid sequence or nucleic acid sequence, SEQ.ID.NO: 1 said segment is defined as recombinant vector in a recombinant host cell.

Dugger et al disclose an isolated nucleic acid segment in figure 2. The nucleic acid segment comprises a first isolated coding sequence that encodes a peptide that is 100% identical to the amino acid sequence SEQ.ID.NO: 2 (see attached sequence alignment in Accession number: U39835) and nucleic acid sequence is 100% identical to SEQ.ID.NO: 1 (see attached sequence alignment in Accession number: U39835). The isolated nucleic acid segment was constructed in a recombinant vector ZAPII (recombinant vector of claim 13) and positive clones were transformed in a prokaryotic host cell, E.coli, (claim 14 and 19) (see abstract and page 485 under Materials and Methods third paragraph through page 486) and the transcript contained an open reading frame encoding a peptide comprising the amino acid sequence MQFSHALIALVAAGLASA (see figure 2) The recombinant host cell further comprises at least a second isolated coding region that encodes a second, distinct Coccidioides spp. Protein, polypeptide or peptide (see internal amino acid sequence, AGVPIDIPPV----AAYL in figure 2). Figure 2 discloses both nucleic acid segments encoding the amino acid sequence SEQ.ID.NO: 2 and Coccidioides peptide and thus read on claims and thus read on claims 1-8, 13-14 and 16-19. The prior art anticipated the claimed invention.

8. The rejection of claims 1-10, 11-19 and 21-23, under 35 U.S.C. 102(b) as being anticipated by Zhu et al 1996 (Infection and Immunity 64', 2695- 2699), Accession numbers: U32518 is maintained as set forth in the previous office action.

Claims are discussed supra.

Zhu et al disclose an isolated nucleic acid, DNA (see abstract and figure 1) comprising a coding region (figure 1, line 3 starts with Methionine) that encodes a peptide that is 100% identical to the amino acid sequence SEQ.ID.NO: 2 (see attached sequence alignment in Accession number: U32518) and nucleic acid sequence is 100% identical to SEQ.ID.NO: 1 (see attached sequence alignment in Accession number: U32518). The pGEX-4T-3-A3 fusion plasmid coding for full length 194 GST fusion protein and was transformed into E.coli, prokaryotic host cell (see page 2696, left column Materials and Methods) and the transcript contained an open reading frame encoding a peptide comprising the amino acid sequence MQFSHALIALVMGLASA. The recombinant host cell further comprises at least a second isolated coding region that encodes a second, distinct Coccidioides spp. Protein, polypeptide or peptide (see internal amino acid sequence, AGVPIDIPPV---AAYL in figure 2). Figure 1 discloses both nucleic acid segment encoding the amino acid sequence SEQ.ID.NO: 2 and a fusion protein (Table 1) and thus read on claims 1-10, 11-19. The E.coli transformed with pGEX-4T-3-A3 plasmid were grown in medium containing IPTG and cells were harvested by centrifugation and suspended in buffer (see page 2696, left column last paragraph) read on composition claims 21-23. Thus the prior art anticipated the claimed invention.

9. The rejection of claims 1-10 and 12-19 and 21-25 under 35 U.S.C. 102(b) as being anticipated by Jiang et al (Infection and Immunity 1999, 67, 5848-5853) is maintained as set forth in the previous office action.

Claims are discussed supra.

Jiang et al disclose an isolated nucleic acid, composition and a vaccine comprising nucleic acid (nucleic acid sequence, SEQ.ID.NO: I) encoding a peptide (amino acid sequence SEQ.ID.NO: 2) in cDNA pVR1012 (expression vector) - Ag2 and IL-12 (adjuvant) cDNA, i.e., adjuvant (page 5849, Materials and Methods, figure 1-2 and tables). Please note that expression vector pVR1012-Ag2 comprises SEQ.ID.NO: 1and encodes SEQ.ID.NO: 2 because Ag2-cDNA encodes full length 194 protein (see page 5849, left column under construction of recombinant plasmids) To prepare Plasmid DNA for immunizations, E.coli (prokaryote) cells were transformed with plasmid containing said Ag-2 DNA. Thus the prior art anticipated the claimed invention as recited in claims 1-10 and 12-19.

The prior art discloses plasmid DNA that was isolated from E.coli transformed with pVR1012- Ag2, pVR1012- -IL-12 and resuspended in buffer (pharmaceutical carrier) and thus it reads on composition/ vaccine comprising said nucleic acid encoding a peptide and an adjuvant IL-12 (see page 5849, under Immunization and challenge) and thus meet the limitations of claims 21-25 (see figure 1 and 2). Thus the prior aft anticipated the claimed invention.

Applicants' arguments for all the rejections filed on 7/26/04 have been fully considered but they are not deemed to be persuasive for the following reasons:

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See Molecular Research Corp. v. CBS, Inc., 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App.1948) ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In re Gray, 53 F. 2d 520, II USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948.

Applicant states that the claimed invention, in the present case, is directed to isolated nucleic acid segments, and related vectors and host cells, in which an isolated coding region encodes a peptide of between 18 and about 24 amino acids in length with a defined amino acid sequence based on SEQ ID NO: 2. Dugger /Zhu/Jiang work is concerned to a full-length protein of 194 amino acids. They do not teach or suggest any isolated peptides of between 18 and about 24 amino acids in length, let alone those based upon SEQ ID NO: 2. Not only is there no identity of invention between Dugger /Zhu/Jiang and the present claims, but the claimed invention represents a surprising and unexpected advance over Dugger, which is implicitly acknowledged by the absence of 103 rejections from the Action.

It is the position of the examiner that the disclosed prior art reads on the claimed invention as stated previously and also in the above paragraph because Dugger/Zhu/Jiang et al disclose an isolated nucleic acid, cDNA (see page486 under Nucleic acid purification & figure2) comprising a coding region that encodes a 194aa polypeptide which includes18 amino acid peptide that is 100% identical to the amino acid sequence SEQ.ID.NO: 2 (see attached sequence alignment in Accession number: U39835) and nucleic acid sequence is 100%

identical to SEQ.ID.NO: 1 (see attached sequence alignment in Accession number: U39835). Further, the disclosed isolated nucleic acid contains overlapping information, still in the form of triplet code and because it is possible to shift the reading frame for any set of triplets by moving the starting point for translation either one or two bases in either direction, two or more amino acid sequences can be encoded by the same region of the nucleic acid chain, the prior art nucleic acid contains second coding region which is distinct yet encoding a second isolated coding region that encodes a second, distinct Coccidioides spp peptide as 194 aa polypeptide comprises several peptides having 18-24aa. The examiner is aware of the claimed invention and therefore, rightly chose to reject the claims under 35 U.S.C. 102(b) because the present claims are broad and therefore, read on the full-length protein.

Applicant states Jiang does not disclose fusion protein or a pharmaceutical or vaccine formulation of the nucleic acid.

The examiner disagrees because Jiang et al disclose plasmid DNA for vaccination that was isolated from E.coli transformed with pVR1012- Ag2, pVR1012- -IL-12 and resuspended in buffer (pharmaceutical carrier) and thus prior art discloses a composition/ vaccine comprising said nucleic acid encoding a peptide and an adjuvant IL-12 (see page 5849, under Immunization and challenge) and thus meet the limitations of claims.

Rejections Based on Amendment for New Claims

Claim Rejections - 35 USC 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C.ÿ102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless _

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See Molecular Research Corp. v. CBS, Inc., 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App.1948) ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In re Gray, 53 F. 2d 520, II USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948).

11. Claims 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Dugger et al (Biochemical and Biophysical Research Communications 218; 485-489), Accession number: U39835.

The claims are drawn to an isolated nucleic acid molecule comprising an isolated coding region that encodes a peptide having the amino acid sequence of SEQ.ID.NO: 2, said nucleic acid comprises either encoding the amino acid sequence or nucleic acid sequence, SEQ.ID.NO: 1, recombinant vector comprising said isolated nucleic acid molecule and a recombinant host cell comprising said vector.

Dugger et al disclose an isolated nucleic acid segment in figure 2. This nucleic acid segment comprises a first isolated coding sequence that encodes a peptide that is 100% identical to the amino acid sequence SEQ.ID.NO: 2 (see attached sequence alignment in Accession number: U39835) and nucleic acid sequence is 100% identical to SEQ.ID.NO: 1 (see attached sequence alignment in Accession number: U39835). This isolated nucleic acid

segment was constructed in a recombinant vector λZAPII (recombinant host cell) and positive clones were transformed in a prokaryotic host cell, E.coli (see abstract and page 485 under Materials and Methods third paragraph through page 486) and the transcript contained an open reading frame encoding a peptide comprising the amino acid sequence MQFSHALIALVAAGLASA (see figure 2). The recombinant host cell further comprises at least a second isolated coding region that encodes a second, distinct Coccidioides spp peptide (see internal amino acid sequence, AGVPIDIPPV----AAYL in figure 2). Figure 2 discloses both nucleic acid coding regions encoding the amino acid sequence SEQ.ID.NO: 2 and a Coccidioides spp peptide and thus read on claims 33-41. The prior art anticipated the claimed invention.

12. Claims 33-41 and 43-44 are rejected under 35 U.S.C. 102(b) as being anticipated by as being anticipated by Zhu et al 1996 (Infection and Immunity 64', 2695- 2699), Accession numbers: U32518.

Claims are discussed supra.

Zhu et al disclose an isolated nucleic acid, DNA (see abstract and figure 1) comprising a coding region (figure 1, line 3 starts with Methionine) that encodes a peptide that is 100% identical to the amino acid sequence SEQ.ID.NO: 2 (see attached sequence alignment in Accession number: U32518) and nucleic acid sequence is 100% identical to SEQ.ID.NO: 1 (see attached sequence alignment in Accession number: U32518). The pGEX-4T-3-A3 (i. e., recombinant host cell) fusion plasmid coding for full length 194 GST fusion protein was transformed into E.coli, prokaryotic host cell (see page 2696, left column Materials and Methods) and the transcript contained in an open reading frame encoding a peptide comprising the amino acid sequence MQFSHALIALVMGLASA and thus read on claims 33-41. The recombinant host cell further comprises at least a second isolated coding region that encodes a

second, distinct Coccidioides peptide (see internal amino acid sequence, AGVPIDIPPV---AAYL in figure 2). Figure 1 discloses both nucleic acid segment encoding a Coccidioides peptide and a fusion protein (Table 1). The E.coli transformed with pGEX-4T-3-A3 plasmid were grown in medium containing IPTG and cells were harvested by centrifugation and suspended in buffer, i.e., pharmaceutical carrier (see page 2696, left column last paragraph) and thus the pellet encoding said composition in buffer read on claims 43-44. Thus the prior art anticipated the claimed invention.

13. Claims 33-41 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Jiang et al (Infection and Immunity 1999, 67, 5848-5853).

Claims are discussed supra.

Jiang et al disclose an isolated nucleic acid, composition and a vaccine comprising nucleic acid (nucleic acid sequence, SEQ.ID.NO: I) encoding a peptide (amino acid sequence SEQ.ID.NO: 2) in cDNA pVR1012 (recombinant host cell) - Ag2 and IL-12 (adjuvant) cDNA, (page 5849, Materials and Methods, figure 1-2 and tables). Please note that expression vector pVR1012-Ag2 comprises SEQ.ID.NO: 1and encodes SEQ.ID.NO: 2 because Ag2-cDNA encodes full length 194 protein (see page 5849, left column under construction of recombinant plasmids) To prepare Plasmid DNA for immunizations, E.coli (prokaryote) cells were transformed with plasmid containing said Ag-2 DNA. Thus the prior art anticipated the claimed invention as recited in claims 33-41.

The prior art also discloses isolated plasmid DNA (from E.coli transformed with pVR1012- Ag2, pVR1012- -IL-12) in buffer (pharmaceutical carrier) and thus it reads on composition/ vaccine comprising said nucleic acid encoding a peptide and an adjuvant IL-12 (see page 5849, under Immunization and challenge) and thus meet the limitations of claims 43-45 (see figure 1 and 2). Thus the prior aft anticipated the claimed invention.

Remarks

14. No claims are allowed.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP706.07 (a). Applicant is reminded of the extension of time policy as set forth in 37 CFR1.136 (a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR1.136 (a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

16. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before final amendments is (703) 872Ä9306. The RightFax number for submission of after final amendments is (703) 872-9307.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272Ä0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each biweek. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

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SUPERVISORY PATENT EXAMINER
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